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EXAMINER	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte FEN HUANG,
CHRISTINE ANDREWS and JOHN SHULTZ

Appeal 2010-000323
Application 10/666,366
Technology Center 1600

Decided: June 2, 2010

Before LORA M. GREEN, FRANCISCO C. PRATS, and
JEFFREY N. FREDMAN, *Administrative Patent Judges.*

FREDMAN, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant(s) seek our review under 35 U.S.C. § 134 of the Examiner's final decision rejecting claims 1, 5, 7-10, 14-18, 22, 24-29, 31-35, 37-40, and 42-45. We have jurisdiction over the appeal under 35 U.S.C. § 6(b).

We AFFIRM.

BACKGROUND

Appellants' invention "is directed to methods for protecting ribonucleic acids (RNA) from degradation by ribonucleases (RNases)" (Spec. 1).

Claim 1 is illustrative:

> 1. A method for protecting RNA from enzymatic degradation by RNases, the method comprising:
>
> (a) to a first solution containing RNA or to which RNA will subsequently be added, adding a second solution, the second solution comprising an amount of an RNase inhibitor protein disposed in a buffer that is devoid of reducing agents, to yield a mixture, wherein the amount of RNase inhibitor protein in the second solution is sufficient to protect RNA from enzymatic degradation by RNases, wherein the RNase inhibitor protein is derived from rats, human placentas, or recombinant human placental sources; and then
>
> (b) heating the mixture of step (a) to a temperature no less than about 90°C for a time sufficient to inhibit RNase activity present in the mixture; whereby RNA present in the mixture or subsequently added to the mixture is protected from enzymatic degradation by RNases.

The Examiner relies on the following prior art references as evidence of unpatentability:

Mizutani et al., *Single-step Reverse Transcription-Polymerase Chain Reaction for the Detection of Hepatitis C Virus RNA*, 42(8) MICROBIOL. IMMUNOL. 549-553 (1998).

Ambion, *SUPERase IN: The Right Choice for Protecting your RNA*, 8(2) TECHNOTES (2001).

Appellants appeal the following rejection:

Claims 1, 5, 7-10, 14-18, 22, 24-29, 31-35, 37-40, and 42-45 under 35 U.S.C. § 103(a) as unpatentable over Mizutani and Ambion.

APPELLANTS' CONTENTIONS

Appellants contend that "the Office has not established a *prima facie* case of obviousness, first, because the references are silent with respect to, or teach away from, the claimed methods and, second, because there is no technological reason or motivation to combine the teachings of the prior art" (App. Br. 5). Appellants also "submit that the references in combination fail to teach or suggest all the required elements" (App. Br. 5).

ISSUE

Does the evidence of record support the Examiner's conclusion that it would have been obvious to modify the RT-PCR method of Mizutani to incorporate the use of the RNase inhibitor of Ambion, identified by Ambion as "ideal for use in RT-PCR"?

FACTUAL FINDINGS

We adopt all of the Examiner's findings as our own (*see* Ans. 4-7).

ANALYSIS

We adopt all of the Examiner's reasoning and response to Appellants' arguments as our own (*see* Ans. 7-17). We add the following comments solely for emphasis.

Appellants argue that "Mizutani et al. are silent with respect to protecting RNA and Ambion teaches away from heating RNases" (App. Br. 5). Appellants also argue that "there is no technological reason or motivation to combine the two references to yield the invention as claimed because the references do not teach or suggest any benefit to the combination" (App. Br. 7).

We are not persuaded. Appellants' arguments do not address why the ordinary artisan would have found claim 1 obvious over Ambion and Mizutani. The obviousness as set forth by the Examiner is not based on whether the RNase inhibitor protein remains active at all times during the procedure, but is instead based on the finding that the RNAse inhibitor protein remains active during periods when the RNA is susceptible to degradation. Whether this susceptibility occurs simply before the conversion of the RNA to cDNA in RT-PCR, or this susceptibility occurs after addition of other reagents that may be contaminated with RNAse, the ordinary practitioner, informed by Ambion, would have recognized the desirability for the presence of an RNAse inhibitor such as placental human RNAse inhibitor in the reaction solution to prevent degradation of RNA. Ambion expressly suggests the use of such an RNAse inhibitor in the RT-PCR reaction (Ambion, abstract).

Appellants also argue that "even if the references were to be combined, they fail to teach all the required elements of the claims. The independent claims require heating an RNase for a time sufficient to inhibit RNase activity. The combined references fail to teach heating an RNase for a time sufficient to inhibit RNase activity" (App. Br. 9).

We are not persuaded. Mizutani expressly teaches that, after the initial 60 minute RT reaction, RT-PCR involves heating the sample to a temperature of 95°C for 20 minutes (Mizutani 550, col. 1), which the Examiner reasonably found satisfies the requirement of step (b) of "heating the mixture of step (a) to a temperature no less than about 90°C for a time sufficient to inhibit RNase activity present in the mixture" as required by Claim 1. Appellants have provided no evidence or argument why the heating time and temperature of Mizutani, in combination with the disclosure of RNase inhibitor that is "ideal for use in RT-PCR" taught by Ambion, would not reasonably be expected to satisfy this limitation.

DECISION

We affirm the § 103 rejections for the reasons of record.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1) (2009).

AFFIRMED

alw

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